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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,038	03/28/2001	Lorna Strachan	11000.1037c3	1046

7590 08/21/2003  
SPECKMAN LAW GROUP  
Suite 100  
1501 Western Avenue  
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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/21/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/823,038

Applicant(s)

STRACHAN

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-32 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-32 and 37-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### **Status of Application**

The Request filed on June 26, 2003 for Continued Examination (RCE) under 37 CFR 1.114 of Application 09/823,038 is granted. An action on the RCE follows.

### **Applicants' Amendment**

Applicants' amendment in Paper No. 24 filed on June 26, 2003 has also been entered in full. Claims 13-21, 23, 25, and 33-36 have been canceled. Claims 39-47 have been added. Claims 29-32, and 37-47 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph**

The rejection of claims 29-32, 37, and 38 under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, as set forth in the previous Office Action (Paper No. 21, March 24, 2003), remains. The newly added claims 39-47 are also rejected under 35 U.S.C. §112, 1<sup>st</sup> Paragraph.

Applicants argue that as evidenced by the Declaration of Dr. J. Greg Murison, in vivo administration of the polypeptide of SEQ ID NO: 31 is effective in enhancing an immune response in mice. Applicants further submit that one of skill in the art would reasonably

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expect polypeptide of SEQ ID NO: 33 to have the same functional activity as polypeptide of SEQ ID NO: 31.

Applicants' argument has been fully considered but is not deemed to be persuasive because the Declaration of Dr. J. Greg Murison is insufficient to overcome the rejection. The experiments described in the Declaration merely show that administering SEQ ID NO: 31 to mice causes changes of the cell surface markers of cells isolated from the draining lymph nodes; it does not support the conclusion that administering SEQ ID NO: 31 to mice "enhance an immune response". It is unclear how the effects of "polypeptide of SEQ ID NO: 31" differ from any other antigens, such as polypeptides or compounds. In addition, Table 1 lacks sufficient description and statistical analysis; it does not indicate the units of the numbers in the table. Thus, one cannot evaluate the validity of the data. Furthermore, the comments in the Declaration at page 2, "Please confirm that this correct", "Please confirm that this was truly IgG3 and not IgG1 as used in Expt. 3", cast doubt on the validity of the data provided in the Declaration.

## **Conclusion**

No claims are allowed.

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### **Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Ruixiang Li  
Examiner  
August 20, 2003

**ELIZABETH KEMMERER  
PRIMARY EXAMINER**